510(k) Summary

Date of summary February 15, 2007

FEB 20

Product Name EasyRA Cholesterol Reagent
EasyRA Calcium Reagent

Sponsor Medica Corporation
5 Oak Park Drive
Bedford, MA 01730

Correspondent MDC Associates, LLC
Fran White, Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device

Manufacturer: Roche Diagnostic Systems, Inc.
Product: Cobas Ready Cholesterol Reagent
Cobas Ready Calcium Reagent

Product Attribute	Medica Cholesterol and Calcium Reagents	Roche Cobas Reagents	Substantial Equivalent
Intended use	Cholesterol – clinical chemistry reagent used to provide a quantitative measurement of total cholesterol in human serum using the EasyRA Chemistry Analyzer. Calcium – clinical chemistry reagent used to provide a quantitative measurement of total calcium in human serum using the EasyRA Chemistry Analyzer.	Cholesterol – clinical chemistry reagent used to provide a quantitative measurement of total cholesterol in human serum using the Roche Cobas Chemistry Analyzer. Calcium – clinical chemistry reagent used to provide a quantitative measurement of total calcium in human serum using the Roche Cobas Chemistry Analyzer.	√
Sample	Serum	Serum	√
Test methodology	Cholesterol - EasyRA Analyzer ready-to-use enzyme assay reagents.	Cholesterol - Cobas Chemistry Analyzer Ready to use enzyme assay	√

	Calcium – EasyRA Analyzer ready-to-use reagents using AZO methodology.	reagents . Calcium – Cobas Chemistry Analyzer Ready to use reagents using AZO methodology	

Intended Use

Calcium

EasyRA Calcium Reagent is intended for the quantitative determination of total calcium concentration in serum using the Medica EasyRA Chemistry Analyzer.

For *in-vitro* diagnostic use only. For Professional use only.

Cholesterol

The EasyRA Cholesterol Reagent is intended for the quantitative determination of cholesterol in human serum on the Medica EasyRA Chemistry analyzer in clinical laboratories to screen for elevated cholesterol as a risk factor in coronary artery disease.

For *in-vitro* diagnostic use only. For Professional Use Only.

Methodology

Calcium

The EasyRA Calcium reagent utilizes Arsenazo III, which is very stable and has a high affinity for calcium at neutral pH. Interference from magnesium is eliminated by the addition of 8-hydroxyquinoline-5-sulfonic acid. Arsenazo III reacts with calcium to form a 1:1 blue complex with an absorption maximum at 650 nm. The concentration of calcium is proportional to the intensity of the blue color

Cholesterol

The EasyRA Cholesterol reagent uses the enzymatic Trinder endpoint reaction, which is based on the work of Allain et al. In this method, cholesterol esters are hydrolyzed by cholesterol esterase to cholesterol and fatty acids. Cholesterol is oxidized by cholesterol oxidase to delta 4-cholestenone with the simultaneous production of hydrogen peroxide. In the presence of peroxidase, hydrogen peroxide oxidizes phenol and 4-aminoantipyrine to give a quinoneimine dye colored red. The absorbance of the resulting quinoneimine dye is measured at 520 nm with 600 nm as a blanking wavelength. The intensity of the color produced is proportional to the concentration of cholesterol in the sample.

Performance Data

Linearity

Linearity studies, based on CLSI EP-6A, were performed using NIST-traceable commercial linearity standards on EasyRA Chemistry analyzers. The EasyRA Calcium Reagent is linear from 1mg/dL to 15mg/dL. The EasyRA Cholesterol reagent is linear from 10mg/dL to 600mg/dL.

Within Run Precision

Within run precision; Twenty replicates of three levels of commercial human-based QC material were tested.

EasyRA Calcium Reagent

QC Level	Within Run SD	Within Run CV
mg/dL	mg/dL	%
12.81	0.23	1.8
9.73	0.19	1.9
5.24	0.17	3.3

EasyRA Cholesterol Reagent

QC Level	Within Run SD	Within Run CV
mg/dL	mg/dL	%
215.90	4.13	1.9
168.05	1.76	1.0
105.70	1.34	1.3

Total Precision

Total Imprecision: Duplicate measurements of each of three levels of QC material were tested twice a day for 20 days.

EasyRA Calcium Reagent

QC Level	Total Imprecision (SD)	Total Imprecision (CV)
mg/dL	mg/dL	%
11.78	0.16	1.33
9.03	0.13	1.46
5.95	0.12	1.95

EasyRA Cholesterol Reagent

QC Level	Total Imprecision (SD)	Total Imprecision (CV)
mg/dL	mg/dL	%
168.5	2.5	1.5
302.9	3.6	1.2
106.2	1.3	1.2

Method Comparison
Method comparison was based on EP7-A. At least 40 samples for each analyte were tested in duplicate on the EasyRA Chemistry Analyzer and the Roche COBAS MIRA analyzer.
Both reagents correlated excellently with the predicate device.

Sample Carryover
Sample carryover, within-run drift, was tested based on CLSI EP10-A2. 11 samples that are L (low) M (mid-range) and H (high) in a predefined sequence twice in a single day. There was no evidence of sample carryover

Interference Testing
Testing for interfering substances was based on CLSI EP-7A. The following substances were tested: Hemoglobin to 500 mg/dL; Bilirubin to 20 mg/dL; and Lipemia (using Intralipid).

EasyRA Calcium Reagent

Hemoglobin	no interference up to 500 mg/dL
Bilirubin	no interference up to 20 mg/dL
Triglycerides	no interference up to 2250 mg/dL

EasyRA Cholesterol Reagent

Hemoglobin	no interference up to 500 mg/dL
Bilirubin	no interference up to 5 mg/dL
Lipemia	no interference up to 2250 mg/dL
Glucose	no interference up to 600 mg/dL
Ascorbic Acid	no interference up to 9 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 20 2008

Medica Corp.
c/o Ms. Fran White
MDC Associates, LLC
163 Cabot Street
Beverly, MA 01915

Re: k072249
Trade Name: EasyRA Calcium Reagent, EasyRA Cholesterol Reagent
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CJY, CHH
Dated: January 31, 2008
Received: February 05, 2008

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072249

Device Name: EasyRA Calcium Reagent
EasyRA Cholesterol Reagent

Indications for Use:

EasyRA Calcium
EasyRA Calcium Reagent is intended for the quantitative determination of total calcium concentration in serum using the Medica EasyRA Chemistry Analyzer. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
For *in-vitro* diagnostic use only. For Professional use only.

EasyRA Cholesterol
The EasyRA Cholesterol Reagent is intended for the quantitative determination of cholesterol in human serum on the Medica EasyRA Chemistry analyzer to screen for elevated cholesterol as a risk factor in coronary artery disease.
For *in-vitro* diagnostic use only. For Professional Use Only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072249